DETAILED ACTION

1. Claims 1-13 are pending in this application.

Sequence Requirements

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a) (1) and (a) (2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821-1.825 for the reason(s) set forth below. Full compliance with the sequence rules is required in response to this office action. See specification page 78.

Priority

3. Receipt is acknowledged of amended to the specification regarding priority statement on 1/07/2005.

Drawings

4. No drawings have submitted with this application, however, bib sheet recites 4 pages of drawings and specification page 6 recites brief description of drawings and page 78 refers to figure 1. Correction and clarifications are requested.

Abstract

5. An abstract on a separate sheet has been submitted with amendment filed on 1/07/2005.

Specification

6. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Information Disclosure Statement

7. The information disclosure statement filed 5/6/05 has been considered. An initialed copy is enclosed.

Election/Restrictions

8. Applicants' election without traverse of 3/31/2008 is acknowledged. Applicants elected claims 1, 2, 3, 6, 7 and 8 drawn to an isolated polypeptide and a method of making a peptide.

Claims 4-5 and 9-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-3 and 6-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a written description rejection.**

Claims 1-3 and 6-8 recite a polypeptide comprising at least 8 contiguous amino acids of the protein sequence of SEQ ID NO: 6, wherein said polypeptide has biological activity.

The specification and the claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus the scope of the claims include numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify the members of the genus, and because the genus is highly variant, SEQ ID NO: 6 is insufficient to describe the genus or fragments thereof. For example there is a well- established correlation between structure and function in the art. But in the instant invention the specification does not describe a structure or a function for the claimed species. Thus applicant has not described a function, which is shared by the full length or fragments thereof of SEQ ID NO: 6, which would adequately describe the genus. One skilled in the art would reasonably conclude that the disclosure fails to provide a representative number of

species to describe the genus of the variants. Thus applicant was not in possession of the claimed genus. None of these meet the written description provision of 35 USC 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 3, 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites "under conditions conducive to the expression of said polypeptides", it not clear what comprises the metes and bounds of conditions.

Claim 7 recites "an antimicrobially effective amount", it not clear what applicants intend of said recitation.

Claim 8 recites "an antivirally effective amount", it not clear what applicants intend of said recitation.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-3 and 6-8 are rejected under 35 U.S.C. 102(b) as anticipated by Larrick et al. (US Patent 6,103,888).

Claims 1, 2, 6, 7 and are to an isolated polypeptide and a composition comprising said polypeptide which said polypeptide comprises at least 8 contiguous amino acids of SEQ ID NO: 6 which has biological activity. Claim 3 recites method of making of said peptide.

Note: The specification page 6, describes SEQ ID NO: 6 as Pep714 which is a fragment of polypeptide defined by SEQ ID NO: 3, said SEQ ID NO: 3 is obtained by proteolytic cleavage of FALL-39 proprotein (SEQ ID NO: 1) position C-108 to R-131.

Larrick et al. teach a sequence 100% identical to SEQ ID NO: 6 (see column 29, SEQ ID NO: 2 positions 108-131) which has biological activity and antimicrobial activity (see columns 15-16). Larrick et al. also teach a method making of said peptide (see column 5-6). Larrick et al. teaches carriers and diluents (see column10). Larrick et al. reference anticipates the claimed invention.

Status of the Claims

15. No claims are allowed.

Conclusion

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is 571-272-0863. The examiner can normally be reached on Monday-Friday 7:30 AM-5:00 PM If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Khatol Shahnan-Shah. B.S.,
Pharm, M.S.
Biotechnology Patent Examiner
Art Unit 1645
June 8, 2008

/Shanon A. Foley/
Supervisory Patent Examiner, Art Unit 1645